

EXHIBIT B-12

Revision History for 100193881

Revision #	Description of Change
1	Original Issue

100193881 Mesh Defect to Harm Map

Specification #(s) in which Defect is defined	Defect english	Defect Description english	Product Category	Effect on Use of Released Product	Standardized Hazard	Global Harm	Severity Category
WI-0011126	Identity	Material, structure or color do not match work order (product mix)	all	Product does not meet label requirements of finished product	GN-03, Loss of product traceability	Regulatory Compliance	S4
WI-0011126	abrasions / scrapes	Any abrasion / scrape of the filament surface that leaves spots on the mesh without a loss in burst strength.	all	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126 TM 403-166	1800 - foreign matter	any substance, object, or material which is not a component of the product on the mesh	all	Patient has reaction to material implanted in the body	GN-01, Residual foreign body	Inflammatory or other Unintended Tissue Reaction	S3
WI-0011126 TM403-166	1801 - Defect in weave or knit of mesh	Any knitting defect that leads to a loss of mechanical strength, e.g. burst strength	all non or partially resorbable meshes and implants	mesh fails to provide long lasting support	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126 TM 403-166	1801 - Defect in weave or knit of mesh	Any knitting / weaving / braiding defect that leads to a loss of mechanical strength, e.g. burst / tensile strength	all fully absorbable meshes and implants	mesh fails to support tissue for expected time	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1801 - Defect in weave or knit of mesh	Any knitting / braiding defect that results in a hole	Ethisorb, Vicryl membrane	mesh fails to support tissue for expected time	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1802 - fraying	the edge of the mesh exhibits fraying of the weave / knit	Non-propagating weave construction	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126, TM403-166	1802 - fraying	the edge of the mesh exhibits fraying of the weave / knit	Propagating weave construction	mesh fails to provide long lasting support	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1803 - Loose threads in the weave or knit	Any threads that are above the weave / knit	all	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126, TM403-166	1804 - creased mesh	mesh is folded or bent in such a way that it will not contact a flat surface at all points prior to folding. No loss of strength	all	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126, TM403-166	1805 - damaged mesh	mesh has holes, tears or stains	all non or partially resorbable meshes and implants, except spacer fabric	mesh fails to provide long lasting support	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1805 - damaged mesh	mesh has holes, tears or stains	spacer fabric for Ultrapro Plug	mesh fails to provide long lasting support	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1805 - damaged mesh	mesh has holes tears or stains	Vicryl mesh, Vicryl mesh bag, Vicryl Band, PDS Band, PDS-Microband, PDS cord	mesh fails to support tissue for expected time	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	damaged film	film has holes, tears, or stains	Physiomesb, VHD	hole in Monocryl foil will impair tissue separating properties	PP-02 Damage, Degradation or Deterioration in function	Adhesion Formation	S3

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WI-0011126, TM403-166	damaged film	film has holes, tears, or stains	Dura Patch	hole in film allows Fluid passage.	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1806 - wrong length	dimensions do not conform to requirements	all, except intermediate process formats, e.g. sheets	Product may not meet label size requirements of finished product: regulatory compliance	GN-03, Loss of product traceability	Regulatory Compliance	S4
WI-0011126, TM403-166	1806 - wrong length	dimensions do not conform to requirements	all intermediate process formats, e.g. sheets	no effect on released product	No Hazard Identified	No harm identified	S1
PS603-006	1807 - wrong diameter	Ligatur does not meet diameter requirement	Temporary cardiac pacing wire	Product may not meet label size requirements of finished product: regulatory compliance	GN-03, Loss of product traceability	Regulatory Compliance	S4
WI-0011126, TM403-166	1808 - alignment	Blue stripes must run true to the length of the cut device	UPP, Artisyn	elongation behavior is part of the device design	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126, TM403-166	1808 - alignment	Blue stripes must run true to the length of the cut device	Ultrapro, Proceed	elongation behavior is not part of the device design	No Hazard Identified	No harm identified	S1
WI-0011126, TM403-166	(1812) - spottiness	The film exhibits spottiness when viewed at angles in the light	all films	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126	color variation	slight color difference in mesh or implant that is objectionable, but does not affect performance, cause confusion to identity, or fail to meet requirements	all	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126	delamination	film delaminates from mesh	Proceed, PVP, Physiomes, VHD	For intraperitoneal applications: risk of adhesions	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126	delamination	film delaminates from mesh	Durapatch	Patch is permeable for liquids	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126	delamination	film delaminates from mesh	Ultrapro Comfort Plug	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1
WI-0011126	delamination	film delaminates from mesh	TVT-S	Ethisorb and PDS-film is not laminated and will not bond to Prolene mesh	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
PS MS-013	burst strength	burst strength too low	all	mesh can burst prematurely	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
PS MS-013	elongation	elongation too low	all	mesh is not as flexible as expected	PP-02 , Damage, Degradation or Deterioration in function	Failure of Treatment	S3
PS MS-013	inherent viscosity (IV)	inherent viscosity too low	non or partially resorbable meshes	intraoperative handling more difficult	No Hazard Identified	No harm identified	S1

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PS MS-013	inherent viscosity (IV)	inherent viscosity too low	resorbable meshes	mesh bursts prematurely	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
PS MS-013	suture pull out	suture pull out too low	all	mesh pulls out of fixation	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
PS MS-013	bending stiffness	bending stiffness out of spec	all	intraoperative handling more difficult	No Hazard Identified	No harm identified	S1
WI-0011126	bartack stitch	Bartack stitch incomplete or defective	UPP, UHS	device pieces fall apart	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-0011126	bartack stitch	Bartack stitch thread ends stick out, stitches too loose or tight.	UPP, UHS	Negative impact on customer perception of product quality	No Hazard Identified	No harm identified	S1